

## REMARKS

Please reconsider the rejections of the claims in light of the foregoing amendments and the following arguments and allow the pending claims.

**A. Rejection of claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention.**

The Examiner has rejected claim 11 under 35 U.S.C. § 112, second paragraph, as indefinite, stating that the term “high humidity” recited in claim 11 was vague and indefinite because it is unclear as to what would constitute “high”.

In response to this rejection, Applicants have amended the phrase “high humidity” in claim 11 to read “at least about 80% humidity”. Support for this amendment is found in the specification on page 22, lines 1-5.

Therefore, in light of the amendment to claim 11, the Examiner is respectfully requested to withdraw the rejection of claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite.

**B. Rejection of claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,126,070 to Leifheit et al. in view of U.S. Patent 5,344,017 to Wittrock.**

The Examiner has rejected claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,126,070 to Leifheit *et al.* (“Leifheit”) in view of U.S. Patent 5,344,017 to Wittrock (“Wittrock”).

The Examiner states that Leifheit teaches a self-contained means for bactericidal chlorine dioxide generation, and that Wittrock teaches the use of flexible packaging for the sterilization of medical instruments that contains an indicator for identifying completion of sterilization. The Examiner contends that it would have been obvious to

one of ordinary skill in the art to combine the inventions of the Leifheit and Wittrock patents "because it would provide for highly efficient sterilization while minimizing user handling and human error."

Leifheit is directed to an article that generates and releases chlorine dioxide gas, which can be used as a "general purpose cleaner" (col. 2, line 58) or a "deodorizer (i.e., odor eliminator)" (col 2, line 61). In one embodiment, the article can include an inner pouch of chlorite solution confined within an outer pouch containing an acid activator. When the inner pouch is ruptured, chlorine gas is generated for release from the article and into the surrounding atmosphere.

Claimed uses of the chlorine dioxide generator include a disinfectant wipe (see claim 36), an odor eliminator (see claim 37), and an odor eliminator for use in a clothes dryer (see claim 38). Leifheit does not suggest a chlorine dioxide generator within the confines of a sterilization container. It is meant solely for disinfecting environments that are outside the pouch in which it is initially contained.

Wittrock, on the other hand, teaches a medical instrument sterilization pouch having an indicator which signals the completion of an applied external sterilization process, wherein the medical instruments "closed within a controlled environment" are subjected to "gases, radiation and/or vapors able to penetrate the closed environment" (col. 1, lines 64-66). Wittrock does not suggest or teach the inclusion of a sterilant generator within the sterilization pouch and discloses only external sterilization processes.

In contrast, to either Leifheit or Wittrock, Applicants' invention is a self-sterilizing system, wherein the sterilant is enclosed within a container, having an indicator adapted for detection of sterilization occurring from within the container. Wittrock does not suggest or teach the inclusion of a sterilant generator within the sterilization pouch and discloses only external sterilization processes.

Even if one of ordinary skill in the art were to combine Leifheit and Wittrock, a combination that Applicants contend is not suggested by the prior art, the combination would still not teach or suggest every one of the limitations of the claims of the present application. See MPEP § 2142 - § 2143 (explaining that the prior art references, when combined, must teach or suggest all the claim limitations). One of skill in the art following the teachings of Leifheit and Wittrock would have been led to use the chlorine dioxide generator as an external sterilant placed outside of the sterilization pouch of Wittrock. Therefore, Applicants' claimed limitations of "a sterilant generator that will produce an effective amount of chlorine dioxide gas, said sterilization generator being disposed within said container" (claim 1 and 8) or "providing a generator of a sterilant within the container" (claim 20) are simply not met by the combination of Leifheit and Wittrock.

Therefore, in light of the above arguments, the Examiner is respectfully requested to withdraw the rejection of claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,126,070 to Leifheit et al. in view of U.S. Patent 5,344,017 to Wittrock.

In sum, in view of the foregoing arguments, we respectfully submit that the rejected claims are patentably distinct over the references cited by the Examiner and

meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application.

Respectfully requested,

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